

ISOLA SYSTEM
AcroMed Cable/Wire Pedicle Screw
510(k) SUMMARY

DEC 16 1996

COMPANY: AcroMed Corporation
3303 Carnegie Avenue
Cleveland, OH 44115

TRADENAME: AcroMed Cable/Wire Pedicle Screw

CLASSIFICATION: Spondylolisthesis Spinal Fixation Device
Unclassified, preamendment device system

DESCRIPTION: The AcroMed Cable/Wire Pedicle Screw is a pedicle screw with a modified grooved head and hole through the base of the head. The ISOLA rod is placed on top of the screw so that the rod fits in the groove. The groove is sized to accommodate both the 4.75 mm and 6.35 mm diameter rods.

The AcroMed Cable/Wire Pedicle Screw is intended for use with 18 gauge wire (304.8 mm in length) (K895439), which adjoins the screw to the rod. Alternatively, stainless steel Songer cable (K935481) may be used in place of 18 gauge wire. The wire or cable is threaded through the hole at the base of the screw head and the wire is twisted or the cable is crimped over the top of the rod.

The screw is available in cancellous lengths of 25.0 mm, 30.0 mm, and 35.0 mm.

MATERIAL: The AcroMed Cable/Wire Pedicle Screw is manufactured from implant grade stainless steel conforming to ASTM F1314 specifications. The wire is made from stainless steel conforming to ASTM F1350 specifications. Stainless steel Songer cables are manufactured from stainless steel conforming to ASTM F138 specifications.

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INDICATIONS:

The AcroMed Cable/Wire Pedicle Screw is designed to be utilized with the ISOLA Spine System (K951657). When used with pedicle screws, the ISOLA implants are intended for use in grade 3 or 4 spondylolisthesis at L5-S1 utilizing autologous bone graft and intended to be removed after solid fusion is attained. Levels of attachment for the indication range from L3 to the sacrum.

The ISOLA Spinal System, when not used with pedicle screws, is intended for hook, wire, and/or sacral/ilial screw fixation from T1 to the ilium/sacrum. The non-pedicle screw indications are spondylolisthesis, degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis and kyphosis), tumor, fracture and previous failed surgery.

As a whole, the ISOLA Spinal System is intended for T1-sacral fixation. Screw fixation is from L3-S1.

**PERFORMANCE
DATA:**

Static and fatigue testing show the AcroMed Cable/Wire Pedicle Screw to perform consistent with previously cleared components.

**SUBSTANTIAL
EQUIVALENCE:**

The AcroMed Cable/Wire Pedicle Screw is equivalent to other AcroMed pedicle screws as cleared under K951657 and to the Harrington Lag Screw, manufactured by Zimmer beginning in the 1960's.